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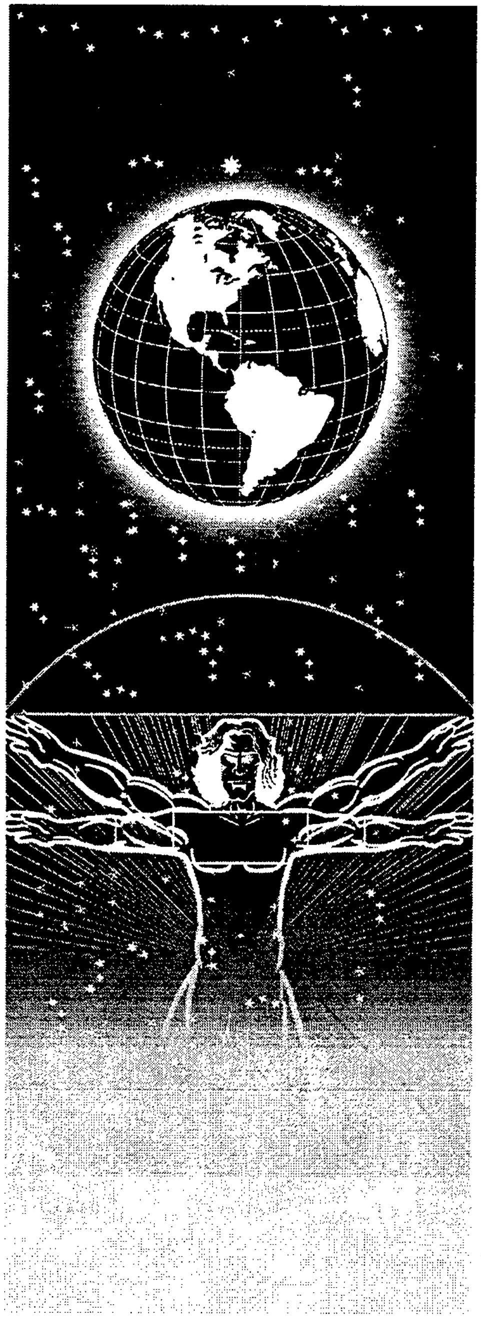

UNITED STATES AIR FORCE
ARMSTRONG LABORATORY

Test and Evaluation of the Laerdal Medical Corp., Laerdal Suction Unit (LSU) 2000/MIL-VAC Suction Unit and Transformer/Rectifier Catalog No. 791700

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September 1997

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NOTICES

This final technical report was submitted by personnel of the Systems Research Branch, Crew Technology Division, Armstrong Laboratory, AFMC, Brooks Air Force Base, Texas, under job order 7184-56-01.

This report has been reviewed and is approved for publication.

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The Laerdal Suction Unit (LSU) 2000/MIL-VAC is a portable oropharyngeal/tracheal suction unit. The LSU is self contained in a hard plastic case and incorporates an internal rechargeable battery. The LSU is powered from the internal battery or a suitable external power source. The LSU is designed to be efficient and user friendly with a minimum of controls and has a 1000ml collection container with tubing storage incorporated in the top of the container.

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TEST AND EVALUATION OF THE LAERDAL MEDICAL CORP., LAERDAL SUCTION UNIT (LSU) 2000/MIL-VAC SUCTION UNIT AND TRANSFORMER/RECTIFIER CATALOG. NO. 791700

BACKGROUND

In August 1994, Laerdal Medical Corporation requested that Armstrong Laboratory evaluate the Laerdal Suction Unit (LSU) 2000/MIL-Vac, Transformer/ Rectifier Catalog No. 791700, and Mascot battery charger to determine their compatibility with aeromedical aircraft systems and the airborne environment.

DESCRIPTION

The Laerdal Suction Unit (LSU) 2000/MIL-Vac is a portable oropharyngeal/ tracheal suction unit and will hereinafter be called the MIL-Vac. Self contained in a hard plastic case (with an integral carrying handle), it incorporates an internal rechargeable battery. The MIL-Vac is powered from the internal battery or a suitable external power source. Suitable power sources include the Laerdal Transformer/ Rectifier Cat. No. 791700 which operates from 115 VAC 60 Hz or 28 VDC through the 12 - 28 VDC power cord. In order to use DC power on USAF aircraft, a Hubbell Twist - Lock® plug, Catalog Number 7545C or equivalent is required to be installed. The MIL-Vac is designed to be efficient and user friendly with a minimum of controls. It has a 1000 ml collection container with tubing storage incorporated in the top of the container. The MIL-Vac specifications are found in Appendix A.

The Laerdal Transformer/Rectifier Catalog No. 791700 converts 115 VAC 60 Hz line voltage to low voltage DC and will hereinafter be called the Transformer/ Rectifier. It operates the MIL-Vac and charges the internal battery.

The Mascot Electronic A/S power supply (battery charger) converts 115 VAC 60 Hz line voltage to low voltage DC to charge the internal battery and will hereinafter be called the Mascot battery charger.

PROCEDURES

Test methods and performance criteria were derived from various military standards (1-3), electrical safety standards (4-5), nationally recognized performance guidelines (6-7), and the MIL-Vac Operating Instructions (9). The Aeromedical Research Procedure's Guide describes additional safety and human interface issues to be considered during equipment testing (8). A test setup and performance check were developed to evaluate the MIL performance throughout testing.

The device was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection
2. Vibration
3. Electromagnetic Interference (EMI)
4. Thermal/ Humidity, encompassing:
   a. Hot Operation
   b. Cold Operation
   c. Humidity
   d. Hot Temperature Storage
   e. Cold Temperature Storage
5. Hypobaric
   a. Cabin Pressure/Altitude
   b. Rapid Decompression to Ambient
6. Airborne Feasibility

INITIAL INSPECTION AND TEST PREPARATION

The baseline performance assessment involves an initial inspection, electrical safety analysis, and following development of a specific test procedure for the device, a baseline performance check.

a. The MIL-Vac, Transformer/Rectifier, and Mascot battery charger were inspected for quality of workmanship, production techniques and possible damage incurred during shipment.

b. The MIL-Vac, Transformer/Rectifier, and Mascot battery charger were checked to ensure they met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (7), Electrical Shock Hazards, AFI 41-203 (8), and Equipment Management in Hospitals, AFI 41-201 (9). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.

c. The MIL-Vac, Transformer/Rectifier, and Mascot battery charger were examined to ensure they met basic requirements for good human factors design as outlined in MIL-STD 1472 (3).

d. A test setup and performance check were developed to evaluate the MIL-Vac's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

Fill 500 ml graduated container with water. Place MIL-Vac suction tube in water filled container and turn suction on for 5 seconds.

PERFORMANCE CHECK

The Performance Check as outlined in the approved test plan was used to validate the function of the MIL-Vac in each of the test conditions. The performance check consisted of checking if the MIL-Vac would suction 500 ml of water in 5 second or less.

Additional laboratory testing validated the following:

1. Occlude the suction tubing and measure the response time from 0 - 300 mmHg.
2. Occlude the suction tubing and measure the response time from 0 - maximum suction.
3. Record the free airflow for low speed operation.
4. Record the free airflow for high speed operation.

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. The safety of everyone on board is a factor of the effects that excessive electromagnetic emissions have on aircraft navigation and communication equipment. Additionally, medical devices may be susceptible to fields generated by the aircraft equipment or other medical devices and malfunction in their presence. A device is approved for use during all phases of flight that include taxi, takeoff, inflight, descent, and landing, or it may be approved for inflight use only.

The MIL-Vac, Transformer/Rectifier, and Mascot battery charger were evaluated for compliance with MIL-STD-461D (5). WL/AAWA-2, Wright-Patterson AFB, performed the evaluation in their electromagnetic compatibility facility in the company of Aeromedical Research and Physio-Control engineers. ASC/ENAI evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102): "Radiated Emissions, Electric Field, 10 kHz to 18 GHz." For Air Force aircraft applications, radiated emissions are tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test determined the amount of EMI emitted by the equipment during its operation. This test must be performed to ensure that the device does not affect other pieces of equipment that may be susceptible to electromagnetic emissions (i.e., aircraft navigation and communication equipment).

b. Conducted Emissions (CE-102): " Conducted Emissions, Power Leads, 10 kHz to 10 MHz." For Air Force aircraft applications, conducted emissions are tested throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the medical device along its power supply lines. This test must be performed to ensure that operating the device using line power does not affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103): "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz." For Air Force aircraft applications, radiated susceptibility is tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (field strength values from Table IV, category Aircraft Internal, of 461D). This test determined whether or not the device would withstand pre-defined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101): "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz." For Air Force aeromedical aircraft applications, conducted susceptibility is tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test determined whether the components would "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."(461D)

e. Conducted Susceptibility (CS-114): "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz." For Air Force aeromedical aircraft applications conducted susceptibility is tested throughout a narrower portion of the frequency band, from 10 kHz to 200 MHz. This test was performed to determine whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."(461D)

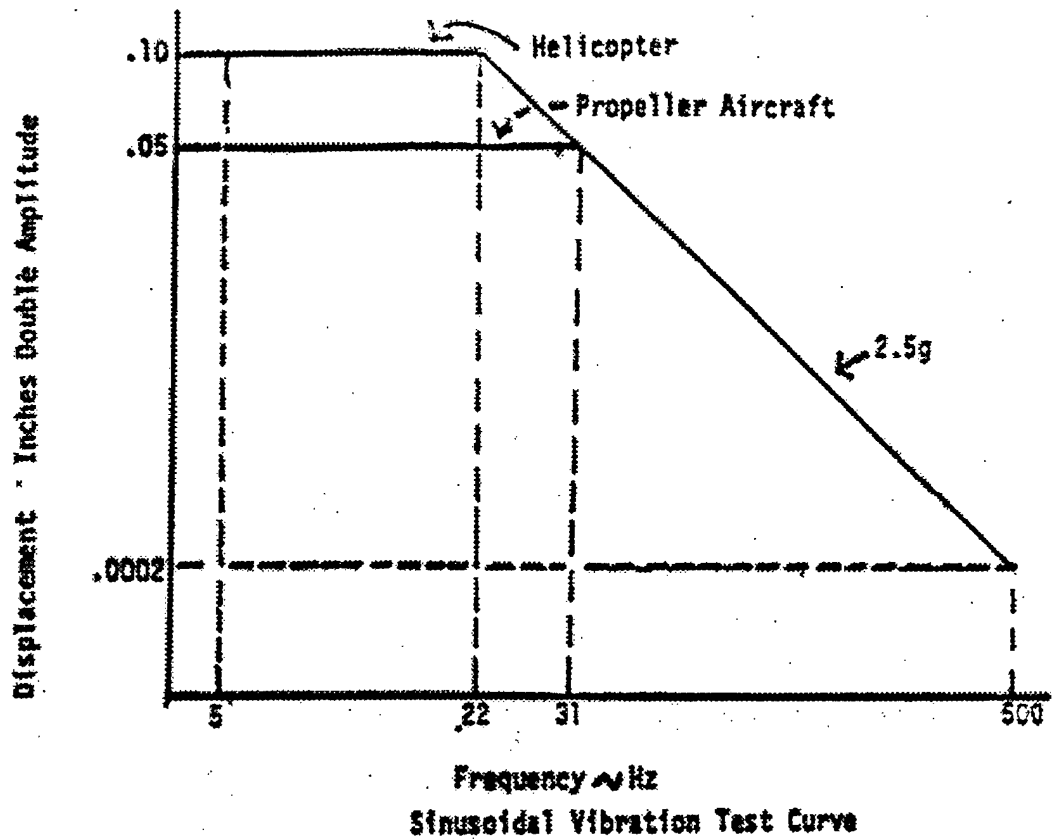
f. Conducted Susceptibility (CS-115): "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation." This test was performed to ensure the MIL-Vac could withstand the "fast rise and fall time that may be present due to platform

switching operations and external transient environments such as lightning and electromagnetic pulse." (461D)

For both emissions and susceptibility testing, the MIL-Vac was tested for operation powered by 115 VAC/60 Hz Transformer/Rectifier, 28 VDC, and internal battery.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (810E). Vibration testing was conducted at Aeromedical Research's vibration facility. This testing involved a set of operational tests performed along each of the MIL-Vac's three axes - X, Y, and Z, with the MIL-Vac, Transformer/Rectifier, and Mascot battery charger mounted on the NATO litter segment on the vibration table as they would be in the aircraft. They were subjected to vibration curves with slightly modified levels and lengths from those depicted in Category 10, Figures 514.4-16 and 514.4-17 of MIL-STD-810E (Figures 3).



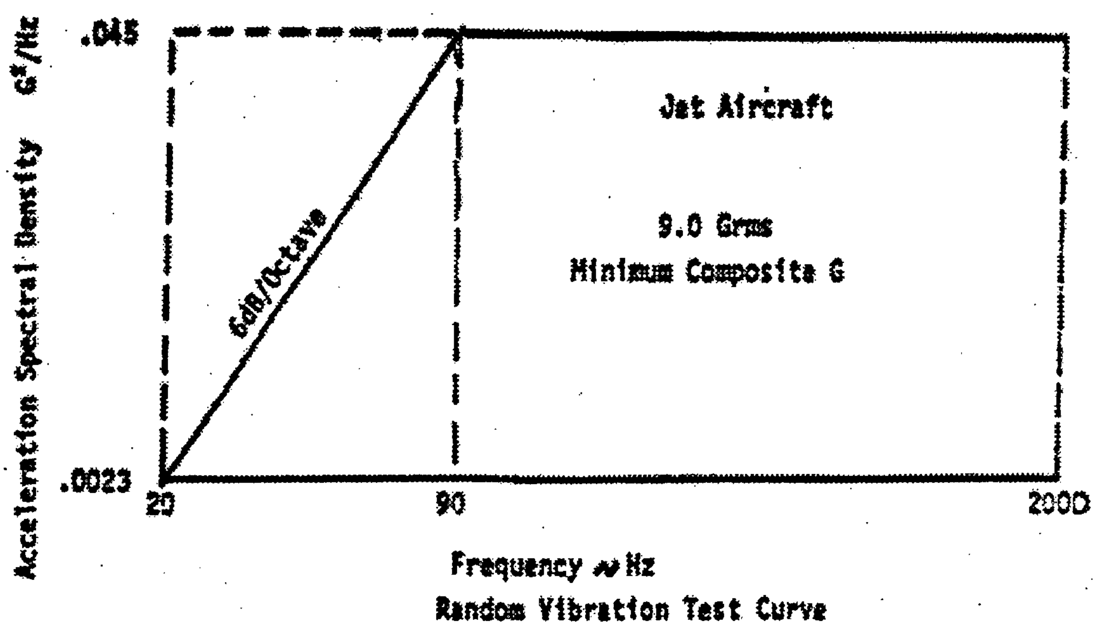


Fig 2. MIL-STD-810E Category 10, figures 514.4-16 and 514.4-17

HYPOBARIC

Testing was conducted in the Armstrong Laboratory research chambers which were operated and monitored by chamber operations personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX.

a. Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft that are characterized as opportune aircraft available for use in aeromedical evacuation pressurize their cabin to barometric pressures equivalent to 8,000-10,000 feet above sea level. However, the differences in pressures can be critical to the effective operation of some medical equipment. The MIL-Vac and Transformer/Rectifier altitude testing consisted of operating the MIL-Vac while ascending from ground level to 10,000 feet (maintaining altitude for one hour) and then descending back to ground, at rates of 5000 ft/min, while stopping at 2000 ft increments to allow for performance checks.

b. Rapid Decompression Testing: Rapid decompressions are caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to determine how medical equipment will function during and after such a decompression and ensure that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The MIL-Vac and Transformer/Rectifier operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft (2,438 meters) altitude. Then, the chamber altitude was brought to 40,000 ft (12,192 meters) over a period of 60 seconds, held at 40,000 ft for a few minutes, and then brought back down to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice with the decompressions occurring over seven and one seconds, respectively. The MIL-Vac and Transformer/Rectifier were monitored throughout the series of decompressions, including performance checks each time the unit returned to ground.

THERMAL/HUMIDITY

Extreme temperature and humidity testing is critical to determine if aeromedical equipment can be stored and operated under severe environmental conditions "without experiencing physical damage or deterioration in performance" (from MIL-STD-810E). Extreme environmental conditions can have numerous detrimental effects on medical equipment including, but not limited to, the following: changes in material characteristics and material dimensions, possible overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water(condensation) or frost formation.

Testing was conducted in the Armstrong Laboratory research chambers operated and monitored by chamber operations personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX. The MIL-Vac and Transformer/Rectifier were placed in the

environmental chamber. The Transformer/Rectifier power cord and suction tubing were routed through a port in the chamber wall which was subsequently sealed with a precut sponge plug. For operational tests, the MIL-Vac and Transformer/Rectifier were monitored continuously, and a performance check was conducted every fifteen minutes. For storage tests, the MIL-Vac and Transformer/Rectifier were placed in the chamber and remained non operational throughout the storage portion of the test. The following describe the conditions of the environmental tests performed:

a. Humidity: 94 ± 4% RH, 85°F ± 3.6°F (29.5°C ± 2°C) for 4 hrs

b. Hot Temp Operation: 120°F ± 3.6°F (49°C ± 2°C) for 2 hrs

c. Cold Temp Operation: 32°F ± 7.2°F (0°C ± 4°C) for 2 hrs

d. Hot Temp Storage: 140°F ± 3.6°F (60°C ± 2°C) for 6 hrs

e. Cold Temp Storage: -40°F ± 3.6°F (-40°C ± 2°C) for 6 hrs

AIRBORNE FEASIBILITY

Airborne feasibility evaluations are an invaluable means of validating an equipment's clinical and operational suitability during actual operating conditions. By carefully evaluating medical equipment items in their actual environment, Aeromedical Research ensures that all pertinent casualty care issues are adequately addressed by the test protocols. Ensuring safe and effective clinical operation of medical equipment is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by an aircraft-qualified aeromedical research technician on board a C-9 aeromedical evacuation mission. The MIL-Vac and Transformer/Rectifier were secured to the litter using two equipment brackets. These items were evaluated throughout the flight by the aeromedical research technician as well as the other members of the aeromedical evacuation crew. It was determined that an evaluation on a C-9 would be representative of most aeromedical evacuation missions. Human factors characteristics, securing methods, and equipment setup times and locations were also evaluated.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection results revealed no manufacturing defects. The MIL-Vac , Transformer/Rectifier, and Mascot battery charger leakage current and ground resistance characteristics remained within allowable limits for battery and

115VAC/60Hz operation. In addition, the baseline performance assessment revealed the following.

Suction capacity:
a. Vacuum regulator set on low: 80 mmHg
b. Vacuum regulator set at midrange: 160 mmHg
c. Vacuum regulator set on high: 540 mmHg

Free airflow at patient end of suction tube:
a. Vacuum regulator set on low: 30.3 LPM
b. Vacuum regulator set at midrange: 30.7 LPM
c. Vacuum regulator set on high: 31 LPM

Time to reach 300 mmHg: 3 seconds or less
Time to suction 500 ml of water: 5 seconds or less

Battery Performance Testing: The MIL-Vac performed satisfactorily during performance testing as outlined in the operating instructions.

ELECTROMAGNETIC COMPATIBILITY

The MIL-Vac, Transformer/Rectifier, and Mascot battery charger passed all phases of electromagnetic compatibility testing in both the operational and charging mode. ASC/ENAI, Wright-Patterson AFB, has currently certified the MIL-Vac for use in aeromedical evacuation on all Air Force aircraft during all phases of flight while operating from battery power, 28 VDC, or the Transformer/Rectifier (115 VAC/60 Hz).

VIBRATION

The MIL-Vac and Transformer/Rectifier operated within manufacturer's specifications throughout the vibration testing. The Mascot battery charger failed vibration testing and the manufacturer did not opt to repair it because battery charging can be provided from the Transformer/Rectifier.

HYPOBARIC

a. Cabin Pressure/Altitude: The MIL-Vac and Transformer/Rectifier operated within manufacturer's specifications during altitude testing.

b. Rapid Decompression: The MIL-Vac and Transformer/Rectifier operated within manufacturer's specifications during all rapid decompression testing.

THERMAL/HUMIDITY

The MIL-Vac and Transformer/Rectifier operated within manufacturer's specifications during all five phases of testing.

AIRBORNE FEASIBILITY

The inflight evaluation of the MIL-Vac and Transformer/Rectifier was performed on a C-9 aeromedical evacuation mission and confirmed that it would operate successfully during all phases of flight. It was secured to a pair of equipment brackets attached to an equipment litter during a portion of the flight. The MIL-Vac was also placed on the floor and secured to a stanchion pole. Analysis of flight data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems.

CONCLUSIONS

Aeromedical Research found the MIL-Vac and Transformer/Rectifier acceptable for use on all Air Force aircraft during all phases of flight while operating from battery power, 28 VDC, or the Transformer/Rectifier (115 VAC/60 Hz).

REFERENCES

1. MIL-STD-461 D, Requirements for the Control of EMI Emissions and Susceptibility.

2. MIL-STD-810 E, Environmental Test Methods and Engineering Guidelines.

3. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.

4. AFI 41-203, Electrical Shock Hazards.

5. AFI 41-201, Equipment Management in Hospitals.

6. National Fire Protection Agency (NFPA) 99, Standard for Health Care Facilities, 1993 version.

7. Emergency Care Research Institute (ECRI)

8. Aeromedical Research Procedures Guide, Internal Operating Instruction, Armstrong Laboratory, Systems Research Branch.

9. Laerdal Suction Unit (LSU) 2000/MIL-Vac Operating Instructions.

APPENDIX A

APPENDIX
LAERDAL MEDICAL CORPORATION
LSU 2000/MIL-VAC SUCTION UNIT
SPECIFICATIONS

Manufacturer:	Laerdal Medical Corporation 167 Myers Corners Road P.O. Box 1840 Wappingers Falls, NY 12590-8840 (800) 648-1851

PHYSICAL CHARACTERISTICS

Dimensions:	130 mm x 350 mm x 235 mm 5.1 in. x13.8 in. x 9.3 in.
Weight:	3.6 kg
Collection Vessel Capacity:	1000 ml
Suction Tubing (non-sterile):	8 mm inside diameter x 1.5 m length

OPERATION

Free Airflow:	>30 liters/minute
Battery Operating Time:	Average of 45 minutes on new fully charged battery
Vacuum - Range:	80 - 500 mmHg
Vacuum - Maximum:	500 mmHg
Gauge Accuracy:	±5 % of full scale

POWER REQUIREMENTS

Operating Power Requirement:	12 - 28 VDC, 5 A max
Power Provided By:	a.) Internal battery b.) 12 - 28 VDC power cord c.) Laerdal Transformer/Rectifier, Catalog No. 791700 (115 VAC 60 Hz)
Battery:	6 VDC, 3.4 Ah rechargeable sealed lead acid
Charging Time:	24 hours (for a fully discharged battery)

ENVIRONMENTAL CONDITIONS

Operating Temperature:	0°C (32°F) to 40°C (104°F)
Long Term Storage Temperature:	0°C (32°F) to 40°C (104°F)
Max 24 h. Storage Temperature:	-30° C (-22°F) to 70°C (158°F)